immunogens;

said mammal thereby receiving, for each said infectious disease, a suitable immunogen in such amounts, given at such ages, as to be effective to substantially prevent or substantially reduce the severity of such infectious disease;

said administering further resulting in an immune response in said mammal sufficient to substantially reduce the incidence of diabetes mellitis in such mammals;

where, when all of the immunogens administered are selected from the group consisting of BCG, diphtheria, tetanus, pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens, for at least one such immunogen, either

(a) a plurality of doses of the immunogen are administered, and such doses are administered less than 28 days apart, or

(b) the immunogen is a live polio virus and at least five doses are given during the first 112 days after birth, or

(c) the immunogen is not a live polio virus, and at least four doses are given during the first 112 days after birth.

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21 (amended). In a method for immunization against at least three infectious diseases, comprising administering at least one pharmaceutically acceptable dose of diphtheria/tetanus/pertussis vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one

pharmaceutically acceptable dose of diphtheria/pertussis/tetanus vaccine, wherein said further administration (a) is according to at least one step selected from the group consisting of

B2 cont

(1) administrating at least two doses of said diphtheria/tetanus/pertussis vaccine at less than 42 days of age of said mammal;

(2) administering said at least one of said dose of said diphtheria/tetanus/pertussis vaccine at less than 42 days of age of said mammal and also administering at least a second dose of said diphtheria/tetanus/pertussis vaccine, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

Sub E3

(3) administering said at least one dose of said diphtheria/tetanus/pertussis vaccine at less than 42 days of age of said mammal and also administering as a total of at least four doses of said diphtheria/tetanus/pertussis vaccine prior to the age of 112 days of said mammal,

wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence [, prevalence, frequency, and severity of at least one chronic immune mediated disorder] of diabetes mellitis [, or at least one surrogate marker of said disorder,] in a population and/or subpopulation of said mammals.

B3

23 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of

Sub E4

diphtheria/tetanus/pertussis vaccine and at least one pharmaceutically acceptable dose of hemophilus influenza vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one of a diphtheria/pertussis/tetanus vaccine and a hemophilus influenza vaccine wherein said further administration (a) is according to at least one method from the group consisting of

(1) administrating at least one dose of both said diphtheria/pertussis/tetanus vaccine and said hemophilus influenza vaccine at less than 42 days of age of said mammal and at least a second dose of at least one said vaccine prior to 42 days of age of said mammal;

(2) administering at least one of said dose of both said diphtheria/tetanus/pertussis vaccine and said hemophilus influenza vaccine at less than 42 days of age of said mammal and also administering at least a second dose of both of said vaccines, wherein said second dose and or any subsequent dose is administered at less than 42 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administering at least one of said dose of both said diphtheria/tetanus/pertussis vaccine and said hemophilus influenza vaccine at less than 42 days of age of said mammal and administrating at least four doses, prior to the age of 112 days, of said mammal for said diphtheria/pertussis/tetanus vaccine or said hemophilus influenza vaccine, [wherein the further administration reduces [at least one measure

selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

B3 Cont'

24 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable first dose of at least one pharmaceutically acceptable immunogen selected from the group consisting of a diphtheria/tetanus/pertussis immunogen, a polio immunogen, a hepatitis B immunogen, a hemophilus influenza immunogen, a non-pediatric immunogen, and a measles/mumps/rubella immunogen, to a mammal after 112 days of age but prior to 724 days of age, the improvement comprising

Sub E4

(a) further administering to said mammal, prior to the age of 112 days, at least one pharmaceutically acceptable second dose containing a greater amount of said immunogen than the amount of immunogen administered as said first dose after 112 days of age but prior to 724 days of age of said mammal, wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

25 (amended). In a method for immunization against at least two infectious diseases, comprising administering at

least one pharmaceutically acceptable dose of a non-whole cell pertussis vaccine to a mammal at least 42 days of age but prior to 724 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen selected from the group consisting of an diphtheria/tetanus immunogen, a non-whole cell pertussis immunogen, a whole cell pertussis immunogen, a polio immunogen, a hemophilus influenza immunogen, a measles/mumps/rubella immunogen and a non-pediatric immunogen, wherein said further administration (a) is according to at least one selected from the group consisting of

(1) administrating said at least one dose of said immunogen at less than 42 days of age of said mammal;

(2) administering said at least one dose of said immunogen, said dose comprising at least a second dose, said second dose or any subsequent said dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administrating at least four doses prior to the age of 112 days of said mammal, wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

26 (amended). In a method for immunization against at

least two infectious diseases, comprising administering at least one pediatric vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable vaccine selected from (i) a combined vaccine containing at least diphtheria, tetanus, pertussis, and hemophilus influenza immunogens, and (ii) a combined vaccine containing at least diphtheria, tetanus, pertussis, and hepatitis B immunogens,

B3 cont

wherein said further administration (a) is according to at least one step selected from the group consisting of

(1) administrating at least of one of said dose of said combined vaccine at less than 42 days of age of said mammal;

Sub E4

(2) administering at least one of said dose of said combined vaccine, said dose comprising at least a second dose, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administrating at least four doses prior to the age of 112 days of said mammal,

wherein the further administration reduces [at least one measure selected from the group consisting of] the incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/ or subpopulation of said mammals.

27 (amended). In a method [of] for immunization against at least two infectious diseases and tolerizing against at least one antigen, comprising administering at least one pharmaceutically acceptable dose of at least one pediatric vaccine to a mammal of at least 42 days of age and administering at least one tolerogen to said mammal,
the improvement comprising

B3 amt

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen selected from the group consisting of an diphtheria/tetanus/pertussis immunogen, a hemophilus influenza immunogen, a measles/mumps/rubella immunogen, a polio immunogen, and a non-pediatric immunogen, wherein said further administration (a) is according to at least one step selected from the group consisting of

(1) administrating said at least one dose of said immunogen at less than 42 day of age of said mammal;

(2) administering said at least one dose of said immunogen, said dose comprising at least a second dose, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than 175 days of age; and

(3) administrating at least four doses prior to the age of 112 days of said mammal,
wherein the further administration reduces the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of

B3 cont

said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

30 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of at least one pediatric vaccine to a mammal of at least 42 days of age,

B4

the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen to said mammal prior to the age of 8 days; and

Sub E6

(b) further administering at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen to said mammal at least 11 days of age but less than 26 days of age,

wherein the further administrations reduce the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or subpopulation of said mammals.

33 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of at least one pharmaceutically acceptable immunogen to a mammal,

B5

the improvement comprising

Sub E7

(A) further administering at least a second pharmaceutically acceptable dose of at least one

pharmaceutically acceptable immunogen, said second dose and or any subsequent dose is administered less than 28 days after the preceding dose,

wherein said (i) second or any subsequent dose contains the same or different immunogens or the same or different amounts of said immunogens as any other dose; (ii) each said separate dose is administered during a 0-78 hour period, and (iii) the further administration reduces the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or at least one surrogate marker of said disorder,] diabetes mellitis in a population and or subpopulation of said mammals.

35 (amended). In a method for immunization against at least two infectious diseases, comprising administering at least one pharmaceutically acceptable dose of hepatitis B vaccine to a mammal of at least 42 days of age, the improvement comprising

(a) further administering to said mammal at least one pharmaceutically acceptable dose of said hepatitis B vaccine according to at least one step selected from the group consisting of

(1) administrating at least 3 said doses of said vaccine at less than 56 days of age of said mammal;

(2) administrating said at least one dose of said vaccine, said dose comprising at least a second dose, said second dose or any subsequent dose administered less than 28 days after the preceding dose when said mammal is less than

175 days of age; and

(3) administrating at least four doses prior to the age of 112 days of said mammal,

wherein the further administration reduces the [at least one measure selected from the group consisting of] incidence[, prevalence, frequency, and severity] of [at least one chronic immune mediated disorder, or of at least one surrogate marker of said disorder,] diabetes mellitis in a population and/or ~~subpopulation of said mammals.~~

37 (amended). A method of immunizing a mammal less than 96 months of age against at least two infectious disease and at least one chronic immune-mediated disorder, comprising

administering to said mammal one or more pharmaceutically acceptable pharmaceutical preparations, comprising one or more immunogens, according to an immunization schedule according to which, at specific times after birth, the mammal receives one or more pharmaceutically acceptable doses of one or more immunogens;

said mammal thereby receiving, for each said infectious disease, a suitable immunogen in such amounts, given at such ages, as to be effective to substantially prevent or substantially reduce the severity of such infectious disease;

said administering further resulting in an immune response in said mammal sufficient to substantially reduce the incidence [or severity] of [at least one chronic immune mediated disorder] diabetes mellitis in such mammal;

the first dose of said immunization schedule including an immune modulator beginning 42 days ~~before~~ after birth,

where said mammal is not immunized with an immunogen in such amounts and at such times as would substantially induce [said immune-mediated disorder] diabetes mellitis.

REMARKS

1. The only substantive rejection in this case is against claims 2-18, 21-35 and 37, for insufficient enablement. However, the Examiner concedes that the disclosure is enabling for "a method [of immunizing] mammals which decreases the incidence of diabetes mellitis". In the interest of speedy resolution, Applicants have amended claims 3, 21, 23-27, 30, 33, 35 and 37 so that all pending claims are limited to the admittedly enabled indication. This is without prejudice or disclaimer to pursuing the subject matter in a continuing application.

2. Certain of the claims were also rejected for indefiniteness.

2.1 Claim 3 has been rewritten in independent form, hence, claims 2-18 are no longer dependent on cancelled claim 1.

2.2 Claim 9 has been amended to refer to claim 3.

2.3 The Examiner states that she is uncertain of what was intended by claim 32. However, the quoted language is from original claim 31, not 32, and does not reflect the correction of "proceeding" to --preceding-- in the last amendment.

An example of an immunization schedule within claim 31 is the following: